K011399

MAY 0 5 2003

BIOMET INC
CORPORATE HEADQUARTERS

Summary of Safety and Effectiveness

Applicant or Sponsor: Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Michelle L. McKinley
Regulatory Specialist

Proprietary Name: Biomet® Craniofacial Acrylic Cement

Common or Usual Name: acrylic cranioplasty material

Classification Name: methyl methacrylate for cranioplasty (882.5300)

Device Product Code: GXP

Substantially Equivalent Devices: Cranioplastic™ Type 1 - Slow Set: K873689

Device Description:

Biomet® Craniofacial Acrylic Cement is a self-curing agent comprised of two sterile components (liquid and powder) packaged in the VacPac®. The components are mixed and delivered from the VacPac® mixing and delivery system forming Biomet® Craniofacial Acrylic Cement.

The powder is composed of: methyl methacrylate – styrene copolymer, poly(methyl methacrylate) beads, and Barium Sulfate, U.S.P.

The liquid is composed of: methyl methacrylate monomer, N,N-dimethyl-p-toluidine, hydroquinone.

Intended Use:

Biomet® Craniofacial Acrylic Cement is indicated for use in repairing cranial defects.

Basis of Substantial Equivalence:

Extensive testing determined that Biomet® Craniofacial Acrylic Cement and CranioPlastic™ have equivalent chemical, handling, physical, and mechanical properties.

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P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
Airport Industrial Park
Warsaw, IN 46580

OFFICE
219.267.6639

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219.267.8137

E-MAIL
biomet@biomet.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 5 2003

Ms. Michelle L. McKinley
Regulatory Specialist
Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, IN 46581-0587

Re: K011399
Trade Name: Biomet® Craniofacial Acrylic Cement
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl methacrylate for cranioplasty
Regulatory Class: II
Product Code: GXP
Dated: February 20, 2003
Received: February 24, 2003

Dear Ms. McKinley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number if Known: K011399
Device Name: Biomet® Craniofacial Acrylic Cement

Indications for Use:

Biomet® Craniofacial Acrylic Cement is indicated for use in repairing of cranial defects.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over the Counter Use _____
(Per CFR 801.109) (Optional Format 1-2-96)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011399